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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/567,702 | 08/21/2006 | Richard Kim | 6750-189-999 | 3898 |
| 20583 | 7590 | 07/16/2009 | EXAMINER | |
| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | HOLLERAN, ANNE L | | |
| | | ART UNIT | | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



Office Action Summary

| | | |
|------------------|------------------|--|
| Application No. | 10/567,702 | |
| Examiner | KIM, RICHARD | |
| ANNE L. HOLLERAN | Art Unit 1643 | |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 September 2008.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2,4,8,10-15,18,22,27,30,34,36 and 47-51 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 2, 4, 8, 10-15, 18, 22, 27, 30, 34, 36 and 47-51 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 207, 12/07, 11/08.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application
6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of species, ErbB2 for the first election of species, and "protein" for the second election of species, in the replies filed on 7/22/2008 and 9/16/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In the amendment filed 9/16/2008, claims 47-51 were added. Claims 2, 4, 8, 10-15, 18, 22, 27, 30, 34, 36 and 47-51 are pending and examined on the merits.

Information Disclosure Statement

Several citations in the IDS received 02/05/08 were lined through by the examiner because they are not in conformance with MPEP 609. The lined through citations lack a publication date.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 8, 10-15, 18, 27, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 27 and 48 are indefinite because of the phrase "therapy regimen for an ErbB-1 positive tumor". It is not clear if this phrase limits the therapy or chemotherapy to a regimen that targets ErbB-1 in particular, or if this phrase is broader in scope and refers to a chemotherapy that is standard for a particular type of cancer, where that particular type of cancer happens to be one that usually expresses ErbB1 (an ErbB-1 positive tumor, such as prostate cancer, for example).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 4, 8, 10, 12 13, 15, 22, 30, 34, 36, 47-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Slamon (US 4,968,603; issued Nov 6, 1990).

Slamon teaches a method of measuring the level of ErbB2 in a sample from a patient, such as a patient with breast cancer that has been treated with surgery. Breast cancer is a cancer that also expresses ErbB1. Slamon teaches that higher levels of ErbB2 protein correlate with a more aggressive phenotype, and a shortened time to relapse (see column 2, lines 22- 35). Slamon teaches a method that further comprises treating a subject based on the patient's risk (claims 20 and 21). Slamon teaches

immunohistochemical detection (see column 4, lines 15-42). Thus, Slamon teaches the claimed methods.

Claims 2, 4, 8, 10, 12, 13, 15, 22, 30, 34, 36, 47-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Ross (US 5,994,701; issued Nov 30, 1999).

Ross teaches a method of measuring the level of ErbB2 in a sample from a patient with prostate cancer, which is an ErbB1 positive cancer, where the measurement of ErbB2 is by the detection of ErbB2 protein levels, and the measurement of ErbB2 provides a prognosis (column 3, line 64 – column 4, line 40). Ross teaches a method that comprises a treatment step because Ross teaches that a physician performing therapeutic regimens (see col. 4, lines 35-40). Therefore Ross teaches the claimed inventions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 4, 8, 10-13, 15, 22, 30, 34, 36, 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slamon (supra) as applied to claims 2, 4, 8, 10, 12, 13, 15, 22, 30, 34, 36, 47-51 above, and further in view of DiGiovanna (DiGiovanna, et al. *Cancer Research*, 55: 1946-1955, 1995).

The claims encompass a method of detecting ErbB-2 receptor related activity, such as phosphorylation of ErbB-2. Slamon does not teach detection of ErbB2 phosphorylation.

However, DiGiovanna teaches that measurement of phosphorylation state allows a more accurate test to determine those patients whose tumors are driven by ErbB2 activity and would likely benefit from an anti-ErbB 2 activity. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Slamon to include a step of measuring ErbB2 receptor related activity, such as phosphorylation level or autophosphorylation activity, which DiGiovanna teaches correlates more closely with a response to therapeutic agents such as an anti-ErbB2 antibody. One would have been motivated by the teaching of DiGiovanna that phosphorylation status of ErbB2 is a more informative predictor of response to treatment using an anti-ErbB2 antibody.

Claims 2, 4, 8, 10, 12, 14, 22, 30, 34, 36, 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slamon (supra) as applied to claims 2, 4, 8, 10, 12, 22, 30, 34, 36, 47-51 above, and further in view of Ballinger (US 6,387,638; issued May 14, 2002).

The claims encompass the use of an ErbB receptor ligand as the ErbB receptor probe.

Slamon teaches as set forth above. Slamon fails to teach the use of an ErbB receptor ligand as an ErbB receptor probe. However, Ballinger teaches the use of heregulin variants (see claim 1, column 97-98) to determine whether a sample contains an ErbB receptor. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Slamon with those of Ballinger to make the claimed methods as they relate to use of an ErbB receptor ligand as the ErbB receptor probe. One would have been motivated by the desire to find those tumors expressing ErbB receptors that had ligand binding ability.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the

Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
December 22, 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643